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10/759,605	01/20/2004	Jan Weber	12013/51401	8100

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EXAMINER	
PELLEGRINO, BRIAN E	

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3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,605	WEBER ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-33 and 36-43* is/are pending in the application.

4a) Of the above claim(s) *6,8,12,14-20,23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9,10,13,21,22,25-33 and 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2010* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 3/31/10 have been fully considered but they are not persuasive. The Examiner first would like to address the drawing objection and Applicant's comments stating it need not show the filter layer covering the entire implant. The Examiner raised the issue of "entire" because the specification failed to explain what the drawings illustrated by "continuous". However, while the Examiner acknowledges the formal drawings, as best understood, the filter layer **14** as presented in Fig. 1, only shows a solid, uninterrupted layer and fails to show it being porous. Therefore if it does not cover an entire surface then why is it shown from end to end? Also it is noteworthy to comment that a layer with **pores** can not be said to cover a layer continuously lying below the porous layer because where a pore is present, it inherently does not cover the material below it because a pore is open space. Therefore, the lack of clear illustration of filter layer being porous and how these pores continuously cover the catalyst has not been addressed. In addition since the issue also pertains to the specification objection, Applicant states the specification need not have exact support or word for word verbatim. However, in this instance the word "continuous" has a well known meaning as defined by *American Heritage Dictionary of the English Language*: Uninterrupted in sequence, substance, or extent. The first issue that arises with this definition in mind is how can something that is uninterrupted be then considered porous? Since the Applicant fails to explain this in the specification, the prior art is

considered "continuous" to the extent that Applicant has a "continuous" porous layer. With respect to the objection of the lack of antecedent basis for describing a "continuous" filter layer, since the claimed layer being called a "filter" has pores, it is imperative Applicant provide support such that it is clear as to what is meant.

In response to Applicant's comments about the claim scope, it is noted that the arguments are not commensurate in scope with the claimed invention. Applicants contend a "continuous" filter layer has no gaps in the filter layer. This argument or what may be an explanation of what Applicants meant by the term "continuous" seems contradictory of the claim language used in claims 1 and 31 stating that the "filter layer" has pores. Gaps can be understood as pores, so how can one say it has no **gaps**? Applicants' assessment of what continuous means would appear to contradict the scope of the claim. Applicant contends that Alt has "gaps" in the filter layer and thus is not considered to be continuous. However, as best understood in view of Applicant's specification, since the filter layer of Alt extends over the extent of the stent surface it can be said to be continuous.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants begin to address the rejection over Alt in view of Narhi et al. and Hehrlein et al. by first stating Alt has an outer "filter layer" that has gaps to release drugs. The teaching of Hehrlein was said to suggest a continuous ceramic coating and

thus Applicants state it would then block or trap the drug from being released because it is a continuous layer and thus render Alt's device inoperable. However, this is an improper assessment because first Applicants make the assumption that the ceramic continuous layer taught by Hehrlein is non-porous. Hehrlein clearly states that the ceramic material can be porous, col. 3 and claim 5. Therefore, Hehrlein can be said to not teach away and make the stent device of Alt inoperable by placing a continuous filter layer thereon.

Drawings

The drawings were received on 3/31/10. These drawings are not acceptable because the issue has not been addressed of how the "continuous **filter** layer" is shown. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "continuous **filter** layer" must be shown or the feature(s) canceled from the claim(s). If layer **14** as explained in Applicant's specification is the **filter** layer of which contains **pores** how can one of ordinary skill comprehend how it is considered to contain **pores** when the filter layer is not even shown with pores, Fig. 1. Applicants state in the response 3/31/10 that the drawing has no "gaps". Gaps can be synonymous with the term pores, thus is a continuous layer mean it does not have pores? No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the implant body is covered by a continuous filter layer was not in the written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites the stent has the filter layer not covering portions of the stent where there is "high strain". However, if the filter layer is recited to be "continuous", it cannot be considered to have regions where it does not exist and thus not cover the stent because this contradicts claim 1 stating a continuous filter layer. To have regions of high strain not covered by the filter layer implies that the filter layer is not continuous.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,7,9,10,13,25-27,29,30,36-38,40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (2004/0039438) in view of Narhi et al. (7527804) and Hehrlein et al. (EP 1319416). Fig. 2 shows an implant body **30** having a first surface covered with a catalyst of metal material **32**, paragraph 32. Coeckelberghs et al. (4752461) teach (col. 5, lines 41-53) that metal ions act as a catalyst to promote the decomposition of hydrogen peroxide to hydrogen and oxygen. Thus, the metal material of Alt is fully capable of being a catalyst as claimed. It can also be seen (Fig. 2) that the catalyst layer of material is covered with a "filter" layer **40** on the porous material **33** and the implant. Alt discloses (paragraph 38) the filter layer has "pores" and since the porous layer it covers has dimensions or pore sizes (paragraph 31) of a microporous

size, it retards white and red blood cells. It is noted that Alt discloses that the filter layer has dimensions of a thickness of 10-50nm, paragraph 37. Regarding claim 7, the catalyst comprises a therapeutic **43**. With respect to claim 26, Alt discloses the catalyst metal can be platinum and can be previously treated, paragraph 32. Regarding claim 30, Alt discloses the base layer is a non-polymer, paragraph 31. However, Alt does not explicitly state the pore size of the filter layer or more specifically 2-50nm. Since the claimed filter layer are pore sizes that fall within dimensions of the thickness of the filter layer of Alt, it would be plausible that the pores of the filter layer of Alt have dimensions as claimed. Narhi et al. teach (col. 5, lines 4-7,44,45,50) that a coated stent can have pore diameters 2-50nm in the porous coating. Narhi et al. further teach that the dimensions of the porous layer enhance the attachment of the layer to the tissue, but prevents encapsulation, which would lead to restenosis, col. 5, lines 21-27. Thus, it would have been obvious to one of ordinary skill in the art to modify the dimensions of the pores in the filter layer of Alt to have dimensions of 2-50nm as taught by Narhi et al. since it would improve the stabilization of the stent within the vessel and prevent narrowing of the vessel. Alt is silent with respect to a continuous filter layer. However, Hehrlein et al. teach the use of a continuous filter layer on the stent, paragraph 6. Hehrlein et al. also teach that the ceramic coating or filter layer improves the integrity of the stent, paragraph 4. It would have been obvious to one of ordinary skill in the art to use a continuous ceramic filter layer as taught by Hehrlein et al. with the stent of Alt as modified with Narhi et al. such that it provides a suitable device that does not cause irritation, but is more stable in the lumen of the patient, Hehrlein. With respect to claims

4,5,25 Alt does not explicitly recite to cover the entire surface of the implant with the catalyst and filter or that regions of high strain when the stent is expanded are not covered. Because the interstices of the outer layers on the stent are used for therapeutic material, it would have been obvious to one of ordinary skill in the art to cover the entire surface with the catalyst and filter material such that it holds more drug material, thus producing predictable results of being able to deliver more therapeutic material to the treatment site. With respect to claim 25 and its limitation of the covering on low strain regions when expanded and not high strain, it is common sense that the more material on an object that is expanding has to exert more force and thus more strain results in that area or region. Therefore it would have been obvious to one of ordinary skill in the art to use less filter material over the high strain regions such that it does not compromise the stent device. Such a modification provides predictable results. Regarding claim 10, Alt does not explicitly recite the porous material is titanium oxide. Narhi et al. '804 teach that one can use titanium oxide coating to enhance tissue acceptance of an implant, col. 5, lines 1-4. It would have been obvious to one of ordinary skill in the art to substitute porous oxide materials and use titanium oxide as taught by Narhi et al. '804 with the stent of Alt '39438 since such a modification only involves routine skill and yields predictable results. With respect to claim 29, Alt does not explicitly state the implant material is a polymer, Narhi et al. teach that alternatively polymers can be substituted for metal implant materials, col. 5, lines 8,9. It would have been obvious to one of ordinary skill in the art to substitute implant materials and use a polymer as taught by Narhi et al. with the stent of Alt since the material could

significantly reduce costs. Additionally, the material could also be substituted to provide a less radiopaque implant that does have interference when using MRI. Regarding claims 41-43 the ceramic coating is Alt's stent is a titanium oxide and Hehrlein also teaches to coat with an alternative oxide, paragraph 4. It is noted that coatings containing titanium can be used on the stent of Alt. Alt can be said to disclose the catalyst is iridium and its oxide is placed on the outer exposed surface. Hehrlein discloses the outer surface is coated with titanium oxide. It would have been an obvious expedient to use alternative oxides and use the teaching of Hehrlein that titanium oxide can be applied to stents and thus use it as the catalyst for the stent of Alt.

Claims 21,22,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (2004/0039438) in view of Narhi et al. '804 and Hehrlein as applied to claim 1 above, and further in view of Smalley et al. (2002/85968). Alt in view of Narhi is explained supra. Alt does disclose the filter material can comprise iridium oxide, paragraph 37. However, Alt fails to disclose alternative filter material or coverings for the composite stent. Smalley et al. teach the use of catalysts with carbon nanotubes or bucky paper coated onto to composites including implants and prostheses, paragraphs 121,276. Smalley also teaches that the bucky paper is useful in supporting catalysts on devices (paragraph 126) and to provide a composite device resisting delamination, paragraph 14. Smalley additionally teaches the bucky paper can be used with oxides, paragraphs 94,166,268. Smalley also teaches that polymers can be applied to enclose the composite material and provide the bulk or support for the body framework, paragraphs 257,259. It would have been obvious to one of ordinary skill in the art to

incorporate bucky paper and a polymer matrix as taught by Smalley et al. with the stent of Alt as modified with Narhi and Hehrlein et al. such that it improves the adherence of the layers formed on the stent material and provide a supportive device that will not collapse or degrade.

Claims 31-33,39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trozera (6475233) in view of Alt et al. (2004/0039438) and Tarhi et al. '804 and Hehrlein et al. (EP 1319416). Trozera shows (Figs. 6a-8c) different strut patterns for stents having a tapered cross-section relative to the longitudinal axis of the stent. Trozera also discloses the stent is expandable, col. 9, lines 26,30. However, Trozera fails to disclose the use of a catalyst and filter layer with pore diameters of 2-50nm. Alt is explained supra. Tarhi et al. is also explained above. Hehrlein et al. is also explained supra. Alt discloses the outer coating layer or oxide aids in reducing inflammation, col. 10, lines 41-47. Tarhi also teaches that the porous coating enhances tissue acceptance and reduces the likelihood of restenosis, col. 5, lines 4-7,21-27. It would have been obvious to one of ordinary skill in the art to incorporate the catalyst and continuous filter material as taught by Hehrlein et al. on the stent as taught by Alt and use pore sizes of 2-50 nm as taught by Narhi et al. such that the stent of Trozera can provide a limited inflammatory response when implanted.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738